

| | | | | | |
|---|---|----|----|---|--|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known Application Number 10/522,525 Filing Date January 26, 2005 First Named Inventor D. WRIGHT Art Unit 1616 Examiner Name Konata M. George Attorney Docket Number 07588.0080-00000 | |
| Sheet | 1 | of | 17 | | |



| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS | | | | | |
|---|-----------------------|--|---|---|---|
| Examiner Initials | Cite No. ¹ | Document Number | Issue or Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number-Kind Code ² (if known) | | | |
| /KG/ | | US-3,698,453 | Oct. 17, 1972 | Morane et al. | |
| | | US-3,970,219 | July 20, 1976 | Spitzer et al. | |
| | | US-4,019,657 | Apr. 26, 1977 | Spitzer et al. | |
| | | US-4,040,420 | Aug. 9, 1977 | Speer | |
| | | US-4,127,131 | Nov. 28, 1978 | Vaillancourt | |
| | | US-4,276,885 | Jul. 7, 1981 | Tickner et al. | |
| | | US-4,292,972 | Oct. 6, 1981 | Pawelchak et al. | |
| | | US-4,466,442 | Aug. 21, 1984 | Hilman et al. | |
| | | US-4,718,433 | Jan. 12, 1988 | Feinstein | |
| | | US-5,064,103 | Nov. 12, 1991 | Bennett | |
| | | US-5,084,011 | Jan. 28, 1992 | Grady | |
| | | US-5,141,738 | Aug. 25, 1992 | Rasor et al. | |
| | | US-5,542,935 | Aug. 6, 1996 | Unger et al. | |
| | | US-5,623,085 | Apr. 22, 1997 | Gebhard et al. | |
| | | US-5,656,200 | Aug. 12, 1997 | Boettcher et al. | |
| | | US-5,676,962 | Oct. 14, 1997 | Garrido et al. | |
| | | US-5,902,225 | May 11, 1999 | Monson | |
| | | US-6,561,237 | May 13, 2003 | Brass et al. | |
| | | US-6,572,873 | June 3, 2003 | Osman et al. | |
| /KG/ | | US-7,025,290 | April 11, 2006 | Osman et al. | |

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|---|--------------------------|
| Examiner Initials | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation ² |
| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| /KG/ | | CA 1 232 837 | Feb. 16, 1988 | | | |
| | | DE 3048744 A1 | Jul. 22, 1982 | | | No |
| | | DE 3050812 C2 | Mar. 21, 1985 | | | No |
| | | DE 8704600.8 | Nov. 26, 1987 | | | No |
| | | DE 3417182 C2 | Jan. 19, 1989 | | | Yes |
| | | EP 0 054 728 A1 | Jun. 30, 1982 | | | Abstract |
| | | EP 0 077 752 | Apr. 27, 1983 | | | Abstract |
| | | EP 0 13 235 | Oct. 31, 1984 | | | Abstract |
| /KG/ | | EP 0 131 540 | Jan. 16, 1985 | | | Abstract |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/522,525 |
| Filing Date | January 26, 2005 |
| First Named Inventor | D. WRIGHT |
| Art Unit | 1616 |
| Examiner Name | Konata M. George |
| Attorney Docket Number | 07588.0080-00000 |

Sheet 2 of 17

FOREIGN PATENT DOCUMENTS

| | | | | | |
|------|-----------------|---------------|--|--|----------|
| /KG/ | EP 0 217 582 A2 | Apr. 8, 1987 | | | |
| | EP 0 324 938 A1 | July 26, 1989 | | | |
| | EP 0 359 246 | Mar. 21, 1990 | | | |
| | EP 0 656 203 A1 | Jun. 7, 1995 | | | |
| | EP 0 997 396 A1 | May 3, 2000 | | | Yes |
| | ES 2 068 151 | Apr. 1, 1995 | | | No |
| | FR 2 672 038 | Jul. 31, 1992 | | | Yes |
| | FR 2 775 436 | Sep. 3, 1999 | | | Yes |
| | FR 1 547 768 | Nov. 29, 1969 | | | No |
| | WO92/05806 | Apr. 16, 1992 | | | |
| | WO95/00120 | Jan. 5, 1995 | | | Abstract |
| | WO96/25194 | Aug. 22, 1996 | | | |
| | WO99/43371 | Sep. 2, 1999 | | | Yes |
| | WO00/24649 | May 4, 2000 | | | |
| | WO00/66274 | Nov. 9, 2000 | | | Yes |
| /KG/ | WO00/72821 A1 | Dec. 7, 2000 | | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation ² |
|-------------------|-----------------------|---|--------------------------|
| /KG/ | | German Nullity Action Complaint filed July 27, 2001. | Yes |
| | | German Nullity Action First Brief filed December 3, 2001. | Yes |
| | | German Nullity Action Supplemental Brief filed December 31, 2002. | Yes |
| | | German Nullity Action Kreusler Brief filed January 27, 2003. | Yes |
| | | German Nullity Action Decision by German Court. | Yes |
| | | German Nullity Action English Translation of the Substantiation of Appeal to the Federal Court of Justice on September 26, 2003. | |
| | | German Nullity Action English Translation of the Reply to appeal dated February 12, 2004. | |
| | | Meyer's Encyclopedia, 5 th Edition, 1895, Vol. 15, pp. 386. | Yes |
| | | R. Bayeux, "Comparative Resistance of Dog and Rabbit to Intravenous Injection of Oxygen", Compt. Rend. Vol. 156, pp. 1329-1331, 1913. | Abstract |
| | | F.W. Tunncliffe et al., "The Intravenous Injection of Oxygen Gas as a Therapeutic Measure", Lancet, Vol. II, pp. 321-323, 1916. | Abstract |
| | | G. Galata, "Intravenous Injection of Oxygen in Dogs", Archivio di Fisiologia, Vol. 21, pp. 331-350, 1923. | Abstract |
| | | L. Moszkowicz, "Treatment of Varicose Veins with Sugar Injections, combined with vein ligation", Zentralblatt für Chirurgie, No. 28, pp. 1731-1736, 1927. | Yes |
| /KG/ | | G. de Takats, "Ambulatory Ligation of the Saphenous Vein", The Journal of the American Medical Association, Vol. 94, No. 16, pp. 1194-1197, April 19, 1930. | |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 17

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/522,525 |
| Filing Date | January 26, 2005 |
| First Named Inventor | D. WRIGHT |
| Art Unit | 1616 |
| Examiner Name | Konata M. George |
| Attorney Docket Number | 07588.0080-00000 |

NON PATENT LITERATURE DOCUMENTS

| | | |
|------|--|-----|
| /KG/ | G. de Takats et al., "The Injection Treatment of Varicose Veins", Surgery, Gynecology and Obstetrics, Vol. L, No. 3, pp. 545-561, March 1930. | |
| | De L'Academie des Sciences, Conformement A Une Decision de L'Academie, pp. 890-892, January 1930. | Yes |
| | I.S. Tunick et al., "Sodium Morrhuate as a Sclerosing Agent in the Treatment of Varicose Veins", Annals of Surgery, Vol. XCV, pp. 734-737, 1932. | |
| | H. Jausion, "Glycerine Chromee et Sclerose des Ectasies Veineuses", La Presse Medicale, No. 53, pp. 1061-1063, May 5, 1933. | |
| | G. de Takats et al., "Ligation of the Saphenous Vein", A report on Two Hundred Ambulatory Operations, Archives of Surgery, Vol., 26, No. 1, pp. 72-88, January 1933. | |
| | H. Harkins et al., "Embolism by Air and Oxygen: Comparative Studies", Proceedings of the Society for Experimental Biology and Medicine, Vol. 32, pp. 178-181, 1934-35. | |
| | L. Ferguson, "Ligation of Varicose Veins, Ambulatory Treatment Preliminary to Sclerosing Injections", Annals of Surgery, Vol. CII, pp. 304-314, 1935. | |
| | A. Ochsner et al., "Comparative Value of Intravenous Sclerosing Substances", Archives of Surgery, Vol. 29, No. 3, pp. 397-416, September 1934. | |
| | H. Biegeleisen, "Fatty Acid Solutions for the Injection Treatment of Varicose Veins", Annals of Surgery, Vol. CV, pp. 610-615, 1937. | |
| | A. Schmier, "Clinical Comparison of Sclerosing Solutions in Injection Treatment of Varicose Veins, Delayed Slough: Recurrence of Varices", The American Journal of Surgery, Vol. XXXVI, No. 1, pp. 389-397, April 1937. | |
| | R.M. Moore et al., "Injections of Air and Carbon Dioxide into a Pulmonary Vein", Annals of Surgery, Vol 112, pp. 212-218, 1940. | |
| | W. Heyerdale et al., "Management of Varicose Veins of the Lower Extremities", Annals of Surgery, Vol. 114, pp. 1042-1049, 1941. | |
| | R. Rowden-Foote; "Varicose Veins Hemorrhoids and Other Conditions - Their Treatment by Injection"; London, H.K. Lewis & Co. Ltd.; pp. 13-45, 106-119; 1944. | |
| | E.J. Orbach; "Sclerotherapy of Varicose Veins - Utilization of and Intravenous Air Block"; American Journal of Surgery; Vol. LXVI, No. 3, pp. 362-366; December 1944. | |
| | R.E. Weston et al., "The Influence of Denitrogenation on the Response of Anesthetized Dogs to Intravenously Injected Oxygen", Vol. 26, pp. 837-848, 1946. | |
| | L. Reiner, "The Activity of Anionic Surface Active Compounds in Producing Vascular Obliteration", Surface Active Sclerosing Agents, Proceedings of the Society for Experimental Biology and Medicine, Vol. 62, pp. 49-54, May-June 1946. | |
| | R. Zingg, "Experimental tests with the new sclerosing agent "Geigy", pp. 1-9, 1948. | |
| | R. Foote, "Treatment", Varicose Veins, Chapter 5, p. 65 and 86, 1949. | |
| | K. Sigg, "Newer Aspects of the Technique of Treating Varicosities", Therapeutische Umschau, vol. 6, pp. 127-134, December 1949. | Yes |
| | K. Sigg, "The Ambulatory Treatment of Phlebitis", Schweizerische Medizinische Wochenschrift, Volume 80, No. 2, January 1950. | Yes |
| | E.J. Orbach et al., "The Thrombogenic Property of Foam of a Synthetic Anionic Detergent (Sodium Tetradecyl Sulfate N.N.R.)", Thrombogenic Property of a Detergent, Vol. 1, pp. 237-243, 1950. | |
| | R. Jung, "Injection Treatment of Varicose Veins", Praxis, pp. 195-198, 1950. | Yes |
| | E.J. Orbach, "Contributions to the Therapy of the Varicose Complex", Journal of the International College of Surgeons, pp. 765-771, June 1950. | |
| | H. Rogge, "On the dangers of sclerosing recurring varicose veins", Deutsche Medizinische Wochenschrift, No. 9, page 301, 1950. | Yes |
| | E.J. Orbach et al.; "The Thrombogenic Property of Foam of a Synthetic Anionic Detergent (Sodium Tetradecyl Sulfate N.N.R.)", Angiol 1, pp. 237-243; 1950. | |
| /KG/ | Sigg, "Regarding treatment of varicose veins and their complications", Dermatologica, Vol. 100, | Yes |

| | | | | | |
|---|---|----|----|-------------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | <i>Application Number</i> | 10/522,525 |
| | | | | <i>Filing Date</i> | January 26, 2005 |
| | | | | <i>First Named Inventor</i> | D. WRIGHT |
| | | | | <i>Art Unit</i> | 1616 |
| | | | | <i>Examiner Name</i> | Konata M. George |
| | | | | <i>Attorney Docket Number</i> | 07588.0080-00000 |
| Sheet | 4 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|--|-----|
| /KG/ | | page 317, 1950. | | | |
| | | G. de Takats et al., "Division of the Popliteal Vein In Deep Venous Insufficiency of the Lower Extremities", Society for Vascular Surgery Issue, Vol. 29., No. 3, pp. 342-354, March 1951. | | | |
| | | R.S. Handley, "The Treatment of Varicose Veins", The Practitioner - Diseases of the Veins, No. 993, Vol. 166, pp. 228-235, March 1951. | | | |
| | | H.E. Lockhart-Mummery et al., "Varicose Ulcer - A Study of the Deep Veins with Special Reference to Retrograde Venography", The British Journal of Surgery, Vol. XXXVIII, No. 151, pp. 284-295, January 1951. | | | |
| | | M. Mairano, "Metodo combinato chirurgico-sclerosante o metodo sclerosante semplice nel trattamento delle varici essenziali?" Minerva Chirurgica, Vol. VI, No. 16, pp. 244-247, May 1951. | | | Yes |
| | | E. Orbach, "Leg Ulcers of Vascular Origin and Their Therapy" The American Journal of Surgery, Vol. LXXXI, No. 5, pp. 568-572, May 1951. | | | |
| | | M. Battezzati et al., "Treatment of Lower Limb Varices with Multiple Endermic Ligations and Sclerosant Injections Combined or not with Stripping of the long Saphenous Vein's higher region", Minerva Chirurgica, pp. 936-939, 1952. | | | Yes |
| | | H. Leonhardt, "On the Treatment of Extensive Formation of Varicose Veins with Ligature of the v. Saphena and Varicoid Injection Through Distally Inserted Ureteral Catheter", Ärztliche Wochenschrift, Vol. 7, No. 3, pp. 56-58, January 1952. | | | Yes |
| | | G. Mayer, "The Treatment of Varicose Veins from the point of View of Sclerotherapy, in particularly on the Basis of Vancophline", Münchener Medizinische Wochenschrift, Vol. 16, No. 20, Columns 1037-1039, January 1952. | | | Yes |
| | | H.G. Oden, "Can the Results of the Treatment of Varicose Vains and Ulcus Cruris be Improved?", Münchener, Medizinische Wochenschrift, Vol. 22, No. 8, pp. 364, January 1952. | | | Yes |
| | | P. Piulaches et al., "Pathogenic Considerations on Varicose Veins Developed in Pregnancy", Lyon Chirurgial, Bulletin officiel de la Socirte de Chirurgie de Lyon, Vol. 47, No. 3, pp. 263-278, April 1952. | | | Yes |
| | | P. Jaeger, "The Current Treatment Standard for Crural Ulcer and Varices", Deutsche Medizinische Wochenschrift, Vol. 77, No. 14, pp. 421-425, April 4, 1952. | | | Yes |
| | | K. Sigg, "The Treatment of Varicosities and Accompanying Complications", Angiology, The Journal of Vascular Diseases, Vol. 3, No. 5, pp. 355-379, October 1952. | | | |
| | | H. Wefers et al., "Results of Injection Treatment with Regard to Extreme Varication", Zentralblatt für Chirurgie, Issue No. 43, pp. 1825-1828, 1952. | | | Yes |
| | | K. Sigg, "The Foamed Rubber Compression for Phlebitis and for Phlebitic and Varicose Complications", Die Medizinische, No. 27-28, pp. 910-915, July 1952. | | | Yes |
| | | P. Piulachs et al., "Pathogenic Study of Varicose Veins", Angiology, The Journal of Vascular Diseases, Vol. 4, No. 1, pp. 59-100, February 1953. | | | |
| ✓ | | F. Kunkel, "Medical Journal of Munich", 95 th year of edition, Vol. 30, no. 44, page 53, 1953. | | | Yes |
| /KG/ | | Von Hans Brücke et al., "The combined foam sclerosis of varices", Wiener Medizinische Wochenschrift, Vol. 104, No. 1, pp. 111-113, January 1954. | | | Yes |

| | | | | | |
|---|---|----|----|--------------------------|------------------|
| IDS Form PTO/SB/06: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| | | | | Attorney Docket Number | 07588.0080-00000 |
| Sheet | 5 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|-----|--|
| /KG/ | | G. de Takats et al., "Aneurysms: General Considerations", Angiology, The Journal of Vascular Disease, Vol. 5, No. 3, pp. 173-208, June 1954. | | | |
| | | A. Hauser et al., "Prophylaxis of Phlebitis and Treatment of Varices During Pregnancy", Schweizerische Medizinische Wochenschrift, 84 th year, No. 1, pp. 13-14, January 2, 1954. | | Yes | |
| | | G.D. Lilly et al., "An Evaluation of "High" Lumbar Sympathectomy in Arteriosclerotic Circulatory Insufficiency of the Lower Extremities", Surgery, Original Communications, Vol. 35, No. 1, pp. 40-44, January 1954. | | | |
| | | Maarz, "Nil nocere! Life-Threatening anaphylactic Incidents in Connection with Sclerosing of Varicose Veins", Münchener Medizinische Wochenschrift, Vol. 27, No. 35, 1954. | | Yes | |
| | | E.J. Orbach, "Allergic Tissue Reaction of Catgut, an Aid for the Obliteration of Varicose Veins", The Journal of the International College of Surgeons, Vol. XXII, No. 6, pp. 707-710, December 1954. | | | |
| | | H. Leidinger, "Sclerosation with air-block technique (Varicoid plus Varicoid foam), Medizinische Klinik, pp. 1183-1184, 1954. | | Yes | |
| | | J and P Vacheron, "Essential Varicose Veins on Lower Limbs: Sclerosant Treatment by Streaming", Archives of Cardio-Vascular Diseases, 7 th Year, No. 12, pp. 1033-1038, December 1954. | | Yes | |
| | | A. Ree, "Varicose Vein Treatment with Foam of Etamolin", Dansk Lægeforening, No. 12-15, pp. 452-453, June 1955. | | | |
| | | A. Hübner, "Der Chirurg, Journal for All Fields of Surgical Medicine", 26 th Year of Edition, 1955. | | yes | |
| | | H. Dodd, "The 'Stripping' Operation for Varicose Veins", The Postgraduate Medical Journal, Vol. 31, pp. 73-78, 1955. | | | |
| | | F. Jaeger, "Primary or Secondary Varicose Veins", Die Medizinische, No. 36, pp.1237-1340, September 1955. | | Yes | |
| | | W. Leun et al., "The Limits and Risks of the Sclerotherapy of Varicose Veins", German Medical Weekly Journal, No. 7, pp. 257-260, February 18, 1955. | | Yes | |
| | | F. Schörcher, "For the Practice Varicose Veins and Deep Chronic Crural Thrombosis", Münchener Medizinische Wochenschrift, No 41, pp. 1354-1358, October 14, 1955. | | Yes | |
| | | K. Sigg, "The Treatment of Leg Ulcers", Die Medizinische, No. 17, pp. 646-648, 1955. | | Yes | |
| | | K. Sigg, "Therapeutic Issues - On the Treatment of Vein Thrombosis with Butazolidin", Schweizerische Medizinische Wochenschrift, 65 th year of the edition, No. 11, pp. 261-262, March 12, 1955. | | Yes | |
| | | M.H. Steinberg, "Evaluation of Sotradecol in Sclerotherapy of Varicose Veins", Angiology The Journal of Vascular Diseases, Vol. 6, No. 6, pp. 519-532, December 1955. | | | |
| ↓ | | | | | |
| /KG/ | | P. Koistinen, "Eräitä näkökohtia alaraajojen laskimon-laajentumien hoidosta ja ennusteesta", | | | |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 17

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/522,525 |
| Filing Date | January 26, 2005 |
| First Named Inventor | D. WRIGHT |
| Art Unit | 1616 |
| Examiner Name | Konata M. George |
| Attorney Docket Number | 07588.0080-00000 |

NON PATENT LITERATURE DOCUMENTS

| | | | |
|------|------|---|-----|
| /KG/ | | Duodecim, Vol. LXXII, No. 12, pp. 1000-1015, 1956. | |
| | | Flückiger, P., Brugg, "Non-Surgical Retrograde Sclerosis of Varicose Veins With Varsyl Foam," Schweizerische Medizinische Wochenschrift No. 48, pp. 1368-1370, 1956. | Yes |
| | | R.W. Décoppet, "The Sclerotherapy of Varices with Thrombophilic Patients", Swiss Medical Weekly Journal, 86 th year, No. 20, pp. 509-513, May 19, 1956. | Yes |
| | | R. May, "Impairments and Risks of the Treatment of Varicose Veins", Münchener Medizinische Wochenschrift, No. 1, pp. 13-16, January 1956. | Yes |
| | | E. Rappert, "The Therapy of Varicose Crural Ulcers", Wiener Medizinische Wochenschrift, Vol. 106, No. 48, pp. 999-1000, December 1, 1956. | Yes |
| | | K. Sigg, "Varicose Veins and Deep Seated Chronic Leg Vein Thrombosis" Münchener Medizinische Wochenschrift, Vol. 98, No. 8, pp. 260-263, February 1956. | |
| | | M.J. Oppenheimer et al., "In vivo Visualization of Intracardiac Structures with Gaseous Carbon Dioxide - Cardiovascular-Respiratory Effects and Associated Changes in Blood Chemistry", American Journal of Physiology, Vol. 186, pp. 325-334, July-September 1956. | |
| | | K. Sigg, "Treatment of Superficial and Deep Thrombosis and the Application of Butazolidine", Gynaecologia, Supplementum ad Vol. 144, pp. 19-23, July 2 to 4, 1956. | |
| | | K. Sigg, "A Good Prophylaxis of Thrombosis during Pregnancy, delivery and childbed as well as for Operations can Prevent the Thrombo-Embolism", Münchener Medizinische Wochenschrift, Vol. 99, No. 17, page 581 and 610-613 April 1957. | Yes |
| | | H. Mayer et al., "Angiology: The Aetiology and Treatment of Varicosities of the Lower Extremity," Chirurgische Praxis, pp. 521-528, 1957. | Yes |
| | | T. Durant, et al., "The Safety of Intravascular Carbon Dioxide and its Use for Roentgenologic Visualization of Intracardiac Structures", Annals of Internal Medicine, Vol. 47, No. 2, pp. 191-201, August 1957. | |
| | | R.R. Foote, "Varicose Vein Problems in General Practice", The Practitioner - Medical Etiquette, Vol. 179, No. 179, pp. 59-66, July 1957. | |
| | | E.J. Orbach, "Reappraisal of the Sclerotherapy of Varicose Veins", Angiology - The Journal of Vascular Diseases, Vol. 8, No. 6, pp. 520-527, December 1957. | |
| | | E. Rappert, "The treatment of varicose veins following a phlebitis and thrombosis", Winer Medizinische Wochenschrift, No. 4, pp. 100-101, 1957. | Yes |
| | | G. Savonuzzi et al., "A Therapeutic Method that Combines Sclerosing Agents and Anticoagulants for varicose diseases of the lower limb", Minerva Medical, Vol. XLVIII, No. 24, pp. 1124-1126, March 24, 1957. | Yes |
| ↓ | /KG/ | Von H. Westhues et al., "The Varicose Symptom Complex", Medizinische Klinik, No. 16, pp. 657-660, 1957. | Yes |

| | | | | | |
|--|---|----|----|-------------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/IPTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | <i>Application Number</i> | 10/522,525 |
| | | | | <i>Filing Date</i> | January 26, 2005 |
| | | | | <i>First Named Inventor</i> | D. WRIGHT |
| | | | | <i>Art Unit</i> | 1616 |
| | | | | <i>Examiner Name</i> | Konata M. George |
| | | | | <i>Attorney Docket Number</i> | 07588.0080-00000 |
| Sheet | 7 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|---|--|--|----------|
| /KG/ | | H. Willenegger et al., "Attempt at carrying out Thromboembolism Prophylaxis without Anticoagulants", Schweizerische Medizinische Wochenschrift - Journal Suisse de Medecine, Vol. 87, Supplement for No. 24, pp. 739-748, 1957. | | | Yes |
| | | K. Sigg, "New Approaches to the Treatment of Thrombosis", Angiology - The Journal of Vascular Diseases, Vol. 8, No. 1, pp. 44-59, February 1957. | | | |
| | | K. Sigg et al., "Prophylaxis of Thrombosis during Gravidity", Die Medizinische, No. 12, pp. 420-423, January 1957. | | | Yes |
| | | B. Gyorgy, "Visszér betegség Másodlagos Szövődményeinek Keelése", Orvosi Hetilap, Vol. XCIX, No. 35, pp. 1215-1218, 1958. | | | |
| | | Dr. Hermann Rompp; "Varsyl"; Chemie Lexikon, Vierte Vollig Neu Bearbeitete Auflage; p. 4649 ; 1958. | | | |
| | | F. Jaeger, "Varicose Veins", Deutsche Medizinische Wochenschrift, Vol. 83, No. 30, page 1295, July 1958. | | | Yes |
| | | K. Sigg, "Prevention and Treatment of Thromboembolic Complications", Wiener Medizinische Wochenschrift, No. 10, pp. 206-213, March 1958. | | | Yes |
| | | E. Rappert, "The achievements of surgical therapy of varicose veins and leg ulcers?", Die Medizinische, No. 22. pp. 906-914, May 1958. | | | Yes |
| | | E.J. Orbach, "Has Injection Treatment of Varicose Veins Become Obsolete? ", The Journal of American Medical Association, Vol. 166., No. 16, pp. 1964-1966, April 19, 1958. | | | |
| | | A. Lemaire et al., "Effect of Intra-arterial oxygen injection on blood cholesterol", Therapie, Vol. 13, pp. 395-399, 1958. | | | Abstract |
| | | 69 th Medical Seminar Evening of the Van-Swieten Society in the District Hospital of Villach, pp. 1-2, Meeting of October 30, 1959. | | | |
| | | A. Ree; " The Treatment of Varicose Veins with Etamolin Foam"; Acta Dermato-Venereologica; Vol. 39, pp. 428-432; 1959. | | | |
| | | H. Dodd, "Varicose Veins and Venous Disorders of the Lower Limb", The Irish Journal of Medicinal Science, Sixth Series, No. 400, pp. 162-174, April 1959. | | | |
| | | A. I. S. MacPherson, "The Treatment of Varicose Veins", The Practitioner - Diseases of the Veins, Vol. 183, No. 1093, pp. 11-18, July 1959. | | | |
| | | F.R. Methiesen, "Subclinical Deep Venous Damage After Sclerosing Injection Demonstrated by Phlebography", Acta Chirurgica Scandinavica, Vol. 118, Fasc. 2, pp. 155-166, 1959. | | | |
| ✓ | | C. Olivier, "Surgical Treatment of Trophic Ulcers of the Inferior Members", Journal de Chirurgie, Vol. 78, No. 2, pp. 157-174, October 1959. | | | Yes |
| /KG/ | | K.R. Ramstad et al., "Operative Treatment of Varicose Veins - Follow-up of Patients Treated with ligature/injection and "Stripping" respectively", Tidsskrift for Den Norske Laegeforening, No. | | | Yes |

| | | | | | |
|---|---|----|----|--------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| Sheet | 8 | of | 17 | Attorney Docket Number | 07588.0080-00000 |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|--|----------|
| /KG/ | | 10, pp. 623-625, May 1959. | | | |
| | | V. Gorisch et al., "Expiration of labeled oxygen after intravenous insufflation", Medicina Experimentalis, Vol. 1, pp. 333-338, 1959. | | | Abstract |
| | | H. Dodd, "Vulval Varicose Veins in Pregnancy", Tensile Strength of Arterial Grafts, British Medical Journal, pp. 831-832, March 28, 1959. | | | |
| | | I. Berson, "Sclerotization or surgery in the treatment of varicose veins of the inferior extremities", University Clinic for dermato-venerology, Lausanne, pp. 485-190, 1960. | | | Yes |
| | | J. Marmasse, "Sclerosing Injections in the Saphenofemoral Junction of the Saphenous Veins. Exploration, Injection, Critique.", La Semaine des Hopitaux, Vol. 36, No. 17, pp. 1086-1095, April 1960. | | | Yes |
| | | F.R. Mathiesen, "Treatment of Varicose Veins - Retrograde Injection or Communicant Resection", Nordisk Medicin, Vol. 64, No. 48, pp. 1525-1529, 1960. | | | Yes |
| | | P. Sicard, "Sclerosing Treatment of Varicose Veins of the Lower Limbs", Therapeutics, Vol. 36, No. 2, pp. 127-129, February 1960. | | | Yes |
| | | W. Stern, "Varicose Veins", The Medical Journal of Australia, Vol. II, No. 18, pp. 849-852, October 29, 1960. | | | |
| | | F. Voss, "Special Methods in the Sclerotherapy of Venous Leg Maladies", Zeitschrift für Haut- und Geschlechts-Krankheiten, Vol. XXVII, No. 9, pp. 304-306, 1960. | | | Yes |
| | | W.G. Fegan, "Continuous Uninterrupted Compression Technique of Injecting Varicose Veins", Proceedings of the Royal Society of Medicine, Vol. 53, No. 7, pp. 837-840, July 1960. | | | |
| | | V. Gorisch et al., "Appearance of intravenously given radioactive oxygen in expired air", Naunyn-Schmiedeberg's Archiv fuer Experimentelle Pathologie und Pharmacologie", Vol. 238, pp. 106-107, 1960. | | | Abstract |
| | | K. Sigg et al., "New Sclerosing Substances for Varicose Veins", Munchener Medizinische Wochenschrift, Issue 1, March 1961. | | | Yes |
| | | J.T. Hobbs, "The Treatment of Varicose Veins in Dublin", Clinical Supplement, pp. 57-60, 1961. | | | |
| | | A. Wiedmann, "The Varicose Symptom Complex", Report on the Literature from the years 1955-1960, Part 1, Varices, Der Hautarzt, Vol. 12, No. 9, pp. 385-391, September 1961. | | | Yes |
| | | Von A. Wiedmann, "Varicose Veins", Der Hautarzt, Year 12, No. 10, pp.433-438, October 1961. | | | Yes |
| | | E. Günther, "On the indication and method of sclerotherapy", Ärztliche Fortbildung, Vol. 55, Brochure 22, pp. 1296-1298, November 1961. | | | Yes |
| | | R. Rauhs, "Sclerotherapy, its indications and treatment successes", Klinische Medizin, Issue 1, pp. 5-12, January 1961. | | | Yes |
| /KG/ | | W. Schneider, "Regarding non-operative varicosclerosis", Die Medizinische Welt, Vol. 3, No. | | | Yes |

| | | | | | |
|---|---|----|----|-------------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | <i>Application Number</i> | 10/522,525 |
| | | | | <i>Filing Date</i> | January 26, 2005 |
| | | | | <i>First Named Inventor</i> | D. WRIGHT |
| | | | | <i>Art Unit</i> | 1616 |
| | | | | <i>Examiner Name</i> | Konata M. George |
| <i>Sheet</i> | 9 | of | 17 | <i>Attorney Docket Number</i> | 07588.0080-00000 |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|---|--|--|----------|
| /KG/ | | 5, pp. 225-227, February 1961. | | | |
| | | K. Sigg, "Treatment of Varices, varicose ulcer and thrombosis", Vienna Medical Weekly Journal, No. 6, February 11, 1961. | | | Yes |
| | | L. Gerson, "The Treatment of Varicose Veins, A Critical Study of Choice of Method", Angiology, The Journal of Vascular Diseases, Vol. 13, No. 16, pp. 260-264, 1962. | | | |
| | | W. Maurer, "Is the sclerosing therapy in the case of varicosis advisable in practice?", Therapie der Gegenwart, Issue 5, pp. 242-245, May 1961. | | | Yes |
| | | J.P. Medelman, "History of the Section on Radiology", The Journal of the American Medical Association, Vol. 178, No. 8, pp. 785-911, November 25, 1961. | | | |
| | | H. Dodd, "Varicose Veins and Venous Disorders of the Lower Limb", The Proceedings of the Cardiff Medical Society, pp. 28-45, 1962. | | | |
| | | H.O. Schneider, "Varix Treatment with Modern Sclerosing Agent", Zeitschrift für Haut und Geschlechtskrankheiten, Band XXXIII, Heft No. 5, pp. 163-166, September 1962. | | | Yes |
| | | I. Singh, "Life Without Breathing", Arch. int. Pharmacodyn., Vol. CXXXVII, No. 3-4, pp. 318-330, 1962. | | | |
| | | P. Flückiger et al., "Physical and Biological Pathogenetic Components of Varicosis", Schweizer Medizinische Wochenschrift, No. 45, 1963. | | | |
| | | E.J. Orbach, "Misconceptions and Pitfalls in Sclerosing Therapy of Varicose Veins", Angiology - The Journal of Vascular Diseases, Vol. 14, No. 11, pp. 552-555, November 1963. | | | |
| | | O. Gilje, "Injection Treatment of Varicose Veins", Den norske Lægeforening, No. 17, pp. 1380-1381, September 1963 and translation into English. | | | Yes |
| | | J.C. Luke et al., "Factors in the Improvement of Results in Varicose Vein Surgery", Improved Vein Surgery, Canadian Journal of Surgery, Vol. 6, No. 2, pp. 145-148, April 1963. | | | |
| | | K. Sigg, "Varicosis and Thrombosis during Pregnancy, birth and in childbed", Zentralblatt für Gynäkologie, No. 8, pp. 254-259, February 23, 1963. | | | Yes |
| | | E.C. Emerson, "A Reappraisal of the Injection Treatment of Varicose Veins", Angiology The Journal of Vascular Diseases, Volume 14, No. 1, pp. 8-13, January 1963. | | | |
| | | P. Flückiger et al., "A Contribution to the Techniques for Outpatient Treatment of Varicose Veins", Lecture delivered at the meeting of the German Working Group on Phlebology and the Hamburg Dermatological society on October 20, 1962, Med. Welt 1963, no. 12, pp. 617-621. | | | |
| | | I.M. Aizman, "On the Treatment with Sclerosal Agents of Patients with Varicose Lower Extremities", Xupyrpus, pp. 46-49, 1964. | | | Abstract |
| ↓ /KG/ | | M. Fabi et al., "Un Nuovo Metodo Di Terapia Sclerosante nel Trattamento Delle Varici", L'Arcispedale S. Anna di Ferrara, Book 1, pp. 351-354, 1964. | | | |

| | | | | | |
|--|----|----|----|-------------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | <i>Application Number</i> | 10/522,525 |
| | | | | <i>Filing Date</i> | January 26, 2005 |
| | | | | <i>First Named Inventor</i> | D. WRIGHT |
| | | | | <i>Art Unit</i> | 1616 |
| | | | | <i>Examiner Name</i> | Konata M. George |
| | | | | <i>Attorney Docket Number</i> | 07588.0080-00000 |
| Sheet | 10 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|---|--|--|-----|
| /KG/ | | W.G. Fegan et al., "A Modern approach to the injection treatment of varicose veins and its applications in pregnant patients", American Heart Journal, Vol. 68, No. 4, pp. 757-764, October 1964. | | | |
| | | H.J. Leu et al., "The Modern Conception of Therapy of Varicose Veins", Angiology, The Journal of Vascular Diseases, Vol. 15, No. 9, pp. 371-378, September 1964. | | | |
| | | E.J. Orbach, "A Unified Approach to the Therapy of Varicosities", Angiology, Vol. 15, No. 12, pp. 558-560, December 1964. | | | |
| | | R. Santier, "Sclerosing Therapy of Varicose Veins", Weiner Klinische Wochenschrift, Issue 24, No. 76, pp. 431-434, June 12, 1964. | | | Yes |
| | | W. Schneider et al., "On the histology of the Varicose Injection Treatment in People with new Injection Treatment Agents", Archive for Clinical and Experimental Dermatology, Vol. 220, pp. 234-249, 1964. | | | Yes |
| | | K. Sigg, "Treatment of Varicose Veins in 2-5 days", Dermatologica, Vol. 129, No. 2, pp. 111-117, 1964. | | | Yes |
| | | K. Sigg, "La Profilassi e la terapia delle malattie venose degli arti inferiori mediante la compressione con fasciature e con calze elastiche", Minerva Ginecologica, Vol. 16, No. 19, pp. 817-823, October 15, 1964. | | | Yes |
| | | E.J. Orbach, "Article on Treatment of Teleangiectasias", Zentralblatt für Phlebologie, Heft 1, Band 3, pp. 4-7, February 15, 1964. | | | Yes |
| | | Von H. Pfohl, "On the Sclerosing Treatment of Varicose Veins", Schweizerische Rundschau für Medizin - Revue Suisse de medecine, 54 th year of Edition, No. 29, pp. 868-871, July 22, 1965. | | | Yes |
| | | K. Sigg, "Varicose Vein Therapy", Deutsche Medizinische Wochenschrift, No. 15, pp. 665-666, April 9, 1965. | | | Yes |
| | | R. Tournay, "Indication of the Exclusive Sclerotherapy or the Consecutive Combination Therapy Surgery-Sclerotization of Varicose Veins, Zentralblatt für Phlebologie, Vol. 4, No. 1, pp. 133-142, February 15, 1965. | | | Yes |
| | | E. J. Orbach, "The Place of Injection Therapy in the Treatment of Venous Disorders of the Lower Extremity - with Comments on its Technique", Presented at the Annual Meeting of the International College of Angiology, London, pp. 18-23, July 1965. | | | |
| | | C. Olivier et al., "Reinterventions Performed on Primary Varicose Veins of the Lower Limbs", La Presse Medicale, Vol. 74, No. 26, pp. 1355-1360, May 25, 1966. | | | Yes |
| | | E.J. Orbach, "The Place of Injection Therapy in the Treatment of Venous Disorders of the Lower Extremity - with Comments on its Technique", Angiology - The Journal of Vascular Diseases, Vol. 17, No. 1, pp. 18-23, January 1966. | | | |
| ↓ | | G. Fegan, "The Treatment of Venous Insufficiency During Pregnancy", Varicose Veins - Compression Sclerotherapy, Chapter VII, pp. 93-98, 1967. | | | |
| /KG/ | | | | | |

| | | | | | |
|---|----|----|----|--------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| | | | | Attorney Docket Number | 07588.0080-00000 |
| Sheet | 11 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--|--|----------|
| /KG/ | | M.D.H.-D. Bock; "Varicosis and its Therapy"; Ärztliche Praxis; XIX Volume, No. 60, pp. 2146-2148; 29 July 1967. | Yes |
| | | P. Flückiger, "Intraoperative Varicosclerosis with Sodium Tetradecyl Foam in the Babcock Operation", Zentralblatt für Phlebologie, Heft 1, Band 6, pp. 514-518, February 1967. | Yes |
| | | K. Sigg, "Sclerotherapy in the Treatment of Varicose Veins", Internist, pp. 388-398, 1967. | Yes |
| | | Dr. E. Lunkenheimer; letter to Chem. Fabrik Kreussler & Co.; March 20, 1967. | Yes |
| | | B. Ya Varshavskii, "Mechanism of Changes in Renal Activity Following intravenous oxygen". Vol. 53, No. 2, pp. 173-177, 1967. | Abstract |
| | | O. Henschel; "Die Varizenverödendung – Verödendungstherapie mit Aethoxysklerol – Kreussler"; p. 22; 1968. | Yes |
| | | W.K. Blenkinsopp, "Effect of Injected Sclerosant (Tetradecyl Sulphate of Sodium) on Rat Veins", Angiologica, Vol. 5, No. 6, pp. 386-396, 1968. | |
| | | E. Frugis et al., "Telangiectasia Sclerotherapy of the Lower Limbs", Minerva Dermatologica, Vo. 43, pp. 368-371, 1968. | Yes |
| | | J. Orbach, "Varicose Veins", Medical Trial Technique Quarterly, Vol. XIV, No. 4, pp. 27-38, June 1968. | |
| | | J. Steinacher et al., "Path and Retention Time of a Contrast Medium in the Superficial Venous System under the Conditions of Varix Obliteration. A Study on the method of varix obliteration", Zsch. Haut-Geschl, Vol. 43, No. 9, pp. 369-376, 1968. | Yes |
| | | J.T. Hobbs, "The Treatment of Varicose Veins - A Random Trial of Injection-Compression Therapy Versus Surgery", Brit. J. Surg., Vol. 55, No. 10, pp. 777-780, October 1968. | |
| | | H. Eichenberger, "Results of the Sclerotherapy of Varicose Veins with Hydroxypolyaethoxy-Dodecan", Zentralblatt für Phlebologie, Vol. 8, pp. 181-183, 1969. | Yes |
| | | K. Sigg, "Phleboscclerosis: experience and results", Der Chirurg, Vol. II, No. 40, pp. 487-491, 1969. | Yes |
| | | W. Gillesberger; "The Equipment of the Dermatologist Working in the Field of Phlebology", the Journal for Skin Diseases; Volume 44 (18), pp. 669-674; 1969. | Yes |
| | | B. Stemmer et al., Phlebologie, Vol. 22, No. 2, pp. 151-172, April-June 1969. | Yes |
| | | G. Wesener, "Morphology and new therapies for starburst varicosis and essential telangiectasia", Berufs-Dermatosen, Vol. 17, No. 5, pp. 273-281, October 1969. | Yes |
| | | W.K. Blenkinsopp, "Choice of Sclerosant: An Experimental Study", Angiologica, Vol. 7, No. 3, pp. 182-186, 1970. | |
| /KG/ | | K. Holzegel, "On Sclerosing Agents for Varicose Veins", Zentralblatt für Phlebologie, Vol. 9, pp. | Yes |

| | | | | | |
|---|----|----|----|--------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| | | | | Attorney Docket Number | 07588.0080-00000 |
| Sheet | 12 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|--|----------|
| /KG/ | | 43-53, 1970. | | | |
| | | B. Stemmer, "Comparison of Common Sclerosing Techniques", Zentralblatt für Phlebologie, Vol. 3, pp. 170-176, 1970. | | | |
| | | J. Edmonds-Seal et al., "Air Embolism", Anaesthesia, Vol. 26, No. 2, pp. 202-208, April 1971. | | | |
| | | H.J. Leu et al., "The Combined Surgical-Sclerotic Ambulatory Treatment of Saphenous Varicose Veins", Schweizerische Rundschau für Medizin, Vol. 1, No. 61, pp. 1360-1364, October 31, 1972. | | | Yes |
| | | K. Sigg, "Technical Details about Injecting Varices", Med. Klin., Vol. 67, No. 27/28, pp. 955-959, 1972. | | | Yes |
| | | Z. Salamon, "Sclerosing Agents - Toxicity and Mechanism of Action", Wiadomosci Lekarskie, Vol. 26 (19), pp. 1819-1822, 1973. | | | Yes |
| | | W.G. Fegan, "Conservative Treatment of Varicose Veins", Progr. Surg. Vol. 11, pp. 37-45, 1973. | | | |
| | | P. Flückiger, "Der Erythem-Test im Rahmen der präoperativen Varizenuntersuchung", Praktische Hinweise-Practical Advice, Vol. 3, No. 2, pp. 198-199, 1974. | | | |
| | | S. Efuin et al., "Oxygen Parameters of Blood and Tissues during Intravascular Oxygenation of the Organism", Eksperimental'naya Khirurgiya i Anesteziologiya, Vol. 5, pp. 183-186, 1974. | | | Abstract |
| | | E.J. Orbach, "The importance of removal of postinjection coagula during the course of sclerotherapy of varicose veins", VASA, Vol. 3, No. 4, pp. 475-477, 1974. | | | |
| | | Malyugin, "Influence exerted on the liver by the intraportal administration of oxygen", Farmakologiya, Vol. 37, No. 2, pp. 183-186, 1974. | | | Abstract |
| | | J.T. Hobbs, "Surgery and Sclerotherapy in the Treatment of Varicose Veins", Arch. Surg. Vol. 109, pp. 793-796, December 1974. | | | |
| | | E.J. Orbach et al., "Investigation of the Different Injection Techniques in the Sclerotherapy of Varicose Veins by Minidose and Differential Pressure Phlebography", VASA, Vol. 4, No. 2, pp. 175-183, 1975. | | | |
| | | K. Sigg, "Quick Treatment - a modified Method of Sclerotherapy of Varicose Veins", Zur Diskussion gestellt - Open for Discussion, VASA, Vol. 4, No. 1, pp. 73-78, 1975. | | | |
| | | H.L. Myers, "Injection Therapy for Varicose Veins", The Journal of Family Practice, Vol. 3, No. 5, pp. 531-534, 1976. | | | |
| | | E.J. Orbach, "Controversies and Realities of Therapy for Varicosis", International Surgery, Vol. 62, No. 3, pp. 149-151, March 1977. | | | |
| | | J. Hobbs, "Surgery or Sclerotherapy for Varicose Veins", Archs. Surg. Vol. 109, page 793, 1974. | | | |
| ↓ /KG/ | | P. Ouvry et al., "Aétoxisclerol: First Impressions", Phlébologie, Vol. 31, No. 2, pp. 75-77, 1978. | | | Yes |

| | | | | | |
|---|----|----|----|--------------------------|------------------|
| IDS Form PTO/SB/06: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| Sheet | 13 | of | 17 | Attorney Docket Number | 07588.0080-00000 |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|-----|--|
| /KG/ | | D. Reinharez, "Perforating Vein Sclerosis Technique", Ph Phlébologie, Vol. 31, No. 2, pp. 69-74, 1978. | | Yes | |
| | | K. Sigg et al., "Treating varices with Sclerotherapy", Langenbacks Arch. Chir., Vol. 347, pp. 231-234, 1978. | | Yes | |
| | | E.J. Orbach, "Hazards of Sclerotherapy of Varicose Veins - their prevention and treatment of complications", VASA, Vol. 8, No. 2, pp. 170-173, 1979. | | | |
| | | P. Ouvry et al., "Sclerosant Treatment of Telangiectasias of the Lower Limbs", Phlébologie, Vol. 32, No. 4, pp. 365-370, 1979. | | Yes | |
| | | P. Ouvry et al., "Le Traitement Sclérosant des Télangiectasies des Membres Inférieurs", Phlébologie, Vol. 35, No. 1, pp. 349-359, 1982. | | Yes | |
| | | E.L. Bodian, "Techniques of Sclerotherapy for Sunburst Venous Blemishes", J. Dermatol. Surg. Oncol. Vol. 11, No. 7, pp. 696-704, July 1985. | | | |
| | | D.S. Camara et al., "The Hemodynamic Effects of the Sclerosant Sodium Morrhuate in Dogs", Surgery - Gynecology and Obstetrics, Vol. 161, No. 4, pp. 327-331, October 1985. | | | |
| | | A. Davy et al., "Ostial Incompetence - Sclerosis or Resection?", Phlébologie, Vol. 39, No. 1, pp. 35-45, 1986. | | Yes | |
| | | F.B. Cockett, "Arterial Complications during Surgery and Sclerotherapy of Varicose Veins", Phlebology, Vol. 1, pp. 3-6, 1986. | | | |
| | | M.P. Goldman et al., "Continuing Medical Education (Dermatologic Surgery), Treatment of Telangiectasia: A review", Journal of the American Academy of Dermatology, Vol. 17, No. 2, part 1, pp. 167-182, August 1987. | | | |
| | | E. Morsiani et al., "Effect of Intravenous and Intreperivenous Injections of Sclerosants (Sodium Tetradecyl Sulfate and Hydroxy Polyethoxy Dodecan) on the Rat Femoral Vein", Resesarch in Experimental Medicine, Vol. 187, pp. 439-449, 1987. | | | |
| | | P. Ouvry et al., "Sclerotherapy of Perforating Veins", Phlébologie, Vol. 40, No. 3, pp. 633-641, 1987. | | Yes | |
| | | L. Karmazsin et al., "Experimental Study of Lipid Peroxidation Following Intravenous Oxygen", Kiserletes Orvostudomány, Vol. 39, pp. 342-348, 1987. | | Yes | |
| | | J.T. Hobbs, "Compression Sclerotherapy in Venous Insufficiency", Acta Chir Scand Suppl., Vol. 544, pp. 75-80, 1988. | | | |
| | | Dr. Med. Jože Bandedic; "Varicosclerozation in Phlebological Practice"; The Journal for Doctors, in Clinic and Practice; XXI Volume No. 3, pp. 126-136; January 11, 1989. | | Yes | |
| | | W. DeGroot et al., "Treatment of Varicose Veins: Modern Concepts and Methods", The Journal of Dermatologic Surgery and Oncology, Vol. 15, No. 2, pp. 191-198, February 1989. | | | |
| ↓ | | | | | |
| /KG/ | | M.A. Farina et al., "Outpatient Treatment of Varicose Vein Segments: Two Techniques | | Yes | |

| | | | | | |
|---|----|----|----|--------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| Sheet | 14 | of | 17 | Attorney Docket Number | 07588.0080-00000 |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|---|--|-----|--|
| /KG/ | | Compared", Phlébologie, pp. 1070-1071, 1989. | | | |
| | | D. Gasparini, "Therapeutic Embolization in Pulmonary Hemorrhage", Radiologica Interventistica, Vol. 77, pp. 223-229, 1989. | | Yes | |
| | | G. Hauer, "Diagnostic and Surgical Treatment of Varicose Veins", Herz, Vol. 14, NO. 5, pp. 274-282, 1989. | | Yes | |
| | | K.M. Hördegen, "Concomitant Circulatory Problems in the Arteries or immobility in mostly older patients make outpatient treatment of ulcers more difficult", Schweiz. Med. Wschr., Vol. 119, No. 37, pp. 1264-1269, 1989. | | Yes | |
| | | P.A. Ouvry, "Telangiectasia and Sclerotherapy", J. Dermatol. Surg. Oncol. Vol. 15, No. 2, pp. 177-181, February 1989. | | | |
| | | R.M. Knight et al., "Ultrasonic Guidance of Injections into the Superficial Venous System", Phlebology, pp. 339-341, 1989. | | | |
| | | S.N. Vasdekis et al., "Evaluation of non-invasive and invasive methods in the assessment of short saphenous vein termination", Br. J. Surg., Vol. 76, pp. 929-932, 1989. | | | |
| | | M. Masaki et al., "The destructive effects of sclerosant ethanolamine oleate on mammalian vessel endothelium", Gastroenterologia Japonica, Vol. 25, No. 1, pp. 230-235, February 1990. | | | |
| | | Z.B. Shafi et al., "Factors Affecting High Shear Preparation of Albumin Microspheres", Pharmaceutical Sciences Research Group, page 144P, 1990. | | | |
| | | N. Weindorf et al., "Control of Sclerosis - Treatment for Varicose Veins", Phlébologie, Vol. 43, No. 4, pp. 681-689, 1990. | | Yes | |
| | | M.P. Goldman, M.D. "Variations on Injection Technique", Sclerotherapy: Treatment of Varicose and Telangiectatic Leg Veins, pp. 274-275, 290, 312-323, 1991. | | | |
| | | G. Belcaro et al., "Treatment of Superficial Venous Incompetence with the Savas Technique", Journal des Maladies Vasculaires (Paris), Vol. 16, pp. 23-27, 1991. | | Yes | |
| | | H.R. Bernbach, "Sclerosing Injections Using the Sigg Method", Phlébologie, Vol. 44, No. 1, pp. 31-36, 1991. | | Yes | |
| | | Y.A. Ershov et al., "Variant of an Operation on Enlarged Veins of the Oesophagus and Cardia in Patients with Portal Hypertension Syndrome", Surgery - Monthly Science Practice Journal, Ministry of Health of the Union of Soviet Socialist Republics All-Union Scientific Society of Surgeons, pp. 46-49, September 9, 1991. | | | |
| | | M.P. Goldman, "Sclerotherapy Treatment of Varicose and Telangiectatic Leg Veins", Clinical Methods for Sclerotherapy of Varicose Veins, pp. 274-275, 290, 312 and 323, 1991. | | | |
| | | J.T. Hobbs, "Varicose Veins", ABC of Vascular Diseases, Vol. 303, pp. 707-710, September 21, 1991. | | | |
| /KG/ | | F. Vin, "Echo-Sclerotherapy of the Small Saphenous Vein", Phlébologie, Vol. 44, No. 1, pp. 79- | | Yes | |

| | | | | | |
|---|----|----|----|-------------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | <i>Application Number</i> | 10/522,525 |
| | | | | <i>Filing Date</i> | January 26, 2005 |
| | | | | <i>First Named Inventor</i> | D. WRIGHT |
| | | | | <i>Art Unit</i> | 1616 |
| | | | | <i>Examiner Name</i> | Konata M. George |
| | | | | <i>Attorney Docket Number</i> | 07588.0080-00000 |
| Sheet | 15 | of | 17 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|--|-----|
| /KG/ | | 84, 1991. | | | |
| | | G. Miserey et al., "Sclerose Sous Echographie Dans Certaines Zones a Risques", Phlebologie, Vol. 44, No. 1, pp. 85-96, 1991. | | | |
| | | M. Schadeck et al., "Echotomographie de la Sclerose", Phlebologie, Vol. 44, No. 1, pp. 111-130, 1991. | | | |
| | | R. de Somer-Leroy et al., "Echographie du Creux Poplite Recherche D'Une Arteriole Petite Saphene Avant Sclerotherapie", Phlebologie, Vol. 44, No. 1, pp. 69-78, 1991. | | | |
| | | G. Belcaro et al., "Treatment of Superficial Venous Incompetence with a Hemodynamic Technique on an Outpatient Basis: The SAVAS Technique", Vascular Surgery, pp. 32-36, January/February 1992. | | | |
| | | R. Muller, "The Ambulatory Phlebectomy", Therapeutische Umschau, Vol. 49, No. 7, pp. 447-450, 1992. | | | Yes |
| | | P. Thibault et al., "Recurrent Varicose Veins", Phlebology, Vol. 18, pp. 895-900, 1992. | | | |
| | | G.J. Postma, "Ethanolamine Oleate Injection: Therapeutic and Pharmaceutical Aspects", Journal of the Dutch Association of Hospital Pharmacists, 8 th year, Issue 3, pp. 84-91, September 1992. | | | Yes |
| | | M. Schadeck, "Sclerotherapy in the Child", Phlebologie, Vol. 45, No. 4, pp. 509-512, 1992. | | | Yes |
| | | M. Schadeck; "Ultrasound-controlled Sclerotherapy of the Great Saphenous Veins"; Phlebologie; Vol. 46, No. 4, pp. 673-682, 1993. | | | Yes |
| | | K. Biegeleisen et al., "Inadvertent Intra-Arterial Injection Complicating Ordinary and Ultrasound-Guided Sclerotherapy", Phlebology, Vol. 19, pp. 953-958, 1993. | | | |
| | | M. Schadeck; " Duplex Controlled Sclerosing Treatment of the Great Saphenous Vein"; Phlebol; Vol 25, pp.78-82; 1996. | | | Yes |
| | | Craig F. Feied, MD, FACEP; " Treatment of all Sizes of Varicose Veins and Spider Veins for Healthy, Beautiful Legs. Mechanism of Action of Sclerosing Agents and Rationale for Selection of a Sclerosing solution"; American Vein Institute; 1996. | | | |
| | | " Sulfaproxyline"; The Merck Index, an Encyclopedia of Chemicals, Drugs, and Biologicals, 12 th Edition; p. 1527; 1996. | | | |
| | | J.R. Cabrera et al.; "Extending the Limits of Sclerotherapy: New Sclerosing Products"; Phlebologie; 50 No. 2; pp. 181-188; 1997. | | | Yes |
| | | J. Cabrera Garrido et al. ; "Elargissement de Limites de la Sclérothérapie: Nouveaux Produits Sclérosants"; Phlebologie; Vol. 50, No. 2 ; pp. 181-188 ; 1997. | | | |
| ↓ | | | | | |
| /KG/ | | J. Garcia Mingo, "Venous Sclerosis with Foam 'Foam Medical System'", Revista Española de Medicina y Cirugía Cosmética, Vol. 7, pp. 29-31, 1999. | | | Yes |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT


(Use as many sheets as necessary)

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/522,525 |
| Filing Date | January 26, 2005 |
| First Named Inventor | D. WRIGHT |
| Art Unit | 1616 |
| Examiner Name | Konata M. George |
| Attorney Docket Number | 07588.0080-00000 |

Sheet 16 of 17

NON PATENT LITERATURE DOCUMENTS

| | | |
|---|--|-----|
| /KG/ | Robert J. Min; "Transcatheter Duplex Ultrasound Guided Sclerotherapy"; Abstracts from the 13 th Annual Congress of the American College of Phlebology; November 10-13, 1999. | |
| | J. Cabrera Garrido et al.; "Escleroterapia en Microespuma : Nuevo Concepto en Escleroterapia. Resultados a Largo Plazo."; Revista Panamericana de Flebología y Linfoología; No. 34; pp. 29-37; September 1999. | |
| | A. Cavezzi; "The Use of Sclerosant Foam in Sclerotherapy: possibilities and limits", Management of Venous Disease in the New Millennium, pp. 16-17, July 2000. | |
| | J. Cabrera et al. ; "Treatment of Varicose Long Saphenous Veins with Sclerosant in Microfoam Form: Long-Term Outcomes"; Phlebology; No. 15, pp. 19-23; 2000. | |
| | E. Rabe et al.; " Guidelines to Sclerosing Treatment of Varicose Veins"; Leitlinien der DGP, Phlebologie; Vol. 6, pp. 154-158; 2001. | Yes |
| | D. Goldberg; "Nd : YAG Laser Treatment of Spider Veins"; pp. 284-288; A. Frullini; "Sclerosing Foam with Polidocanol or Sodium Tetradecyl Sulphate in the Treatment of Superficial Venous Insufficiency"; pp. 289-292; J. Cabrera et al.; "Treatment of Varicose Long Saphenous Veins with Sclerosant in Microfoam Form: Long-Term Outcomes"; pp. 293-298 F. Heinrich; "Venous Thrombosis and Pulmonary Embolism during Pregnancy and the Puerperium"; pp. 299-308 F.X. Breu et al. ; "Duplex Scanning of Lipedema and Lymphedema"; pp. 309-320; Scope on Phlebology and Lymphology; Volume 8; Issue 3/4; December 2001. | |
| | Gianni Belcaro; "Micro-sclerotherapy"; Sclerotherapy in Venous Disease; pp. 89-95; 2002 | |
| | A. Frullini et al., "Sclerosing Foam in the Treatment of Varicose Veins and Telangiectases: History and Analysis of Safety and Complications", Dermatol Surg. Vol. 28, No. 1, pp. 11-15, January 2002. | |
| | P. Coleridge Smith, "Foam Sclerotherapy in Treatment of Varicose Veins: Results from Europe", Invited Presentation at Pacific Vascular Symposium, Kona, November 2002. | |
| | A. Cavezzi et al., "Treatment of Varicose Veins by Foam Sclerotherapy: Two Clinical Series", The Venous Forum of the Royal Society of Medicine and Societas Phlebologica Scandinavica, Vol. 17, No. 1, pp. 13-18, November 2002. | |
| | Butler Studies to Date, "Summary of the Butler gas physiology studies to date (13-June 2003)", pp. 1-12. | |
|  | Syllabus & Scientific Abstracts of the UIP World Congress Chapter Meeting, San Diego, California, August 27-31, 2003. | |
| /KG/ | Dr. J.C. Wollmann et al.; Evaluation of the Test; Kreussler Pharma; pp. 17-28, January 29, 2003. | Yes |

| | | | | | |
|---|----|----|----|--------------------------|------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/522,525 |
| | | | | Filing Date | January 26, 2005 |
| | | | | First Named Inventor | D. WRIGHT |
| | | | | Art Unit | 1616 |
| | | | | Examiner Name | Konata M. George |
| Sheet | 17 | of | 17 | Attorney Docket Number | 07588.0080-00000 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|--|---|-----|
| /KG/ | | C. Frullini, et al., "Personal Experience with the Sclerosing Foam in Duplex Guided Sclerotherapy", pp.1-4. | |
| | | "Phlebocid"; CSST – Service du Répertoire Toxicologique; Case Number: 2272-11-9; http://www.reptox.cssst | |
| | | J. Cabrera; "Application Techniques for Sclerosant in Micro-Foam Form"; pp. 39-44. | |
| | | Pr. Dr. R. Höhler; "The Indication of the Rotation Speed and the Duration of the Rotation is not Sufficient for Foams Produced by a Rotating Brush to be Able to Produce a Foam that Has Well-Defined Properties and that Can Be Reproduced." | Yes |
| | | A. Frullini; "Sclerosing Foam in the Treatment of Recurrent Varicose Veins"; Foam Sclerotherapy – State of Art; pp. 73-77. | |

| | | | |
|-----------------------|-----------------|--------------------|------------|
| Examiner Signature | /Konata George/ | Date Considered | 02/11/2008 |
|-----------------------|-----------------|--------------------|------------|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.